REMARKS

Claims 1-24 are pending in the application. The Office Action rejects claim 1-12, 14, 15, 18, 19, and 24. The Office Action objects to claims 13, 16, 17, and 20-23. Claims 1, 5-8 and 23 have been amended. Reconsideration of the previously rejected claims and favorable action is requested in light of the above amendments and the following remarks.

Entry of the amendments/remarks is proper under 37 C.F.R. §1.116 since the amendments: (a) place the application in condition for allowance (for the reasons discussed herein); (b) do not raise any new issues requiring further search and/or consideration (since the amendments amplify issues previously discussed throughout the prosecution); (c) satisfy a requirement of form asserted in the previous Office Action; (d) do not present any additional claims without canceling a corresponding number of finally rejected claims; and (e) place the application in better form for appeal should an appeal be necessary. The amendments are necessary and were not earlier presented because they are made in response to arguments raised in the Final Rejection. Entry of the amendments is thus respectfully requested.

Rejections under 35 U.S.C. § 112, second paragraph

The Office Action rejects claims 6-10 and 12 as being indefinite under 35 U.S.C. § 112.

Specifically referring to claim 6, the term "said fastener" was deemed to lack antecedent basis. Furthermore, in claim 7, the term "said sutures" was deemed to lack antecedent basis. Claims 6 and 7 have been amended to correct these informalities. Withdrawal of the rejection of these claims under 35 U.S.C. § 112, second paragraph is respectfully requested.

Anticipation rejections based on Spence

In the present Office Action, claims 1, 5-7, 11, 14 and 14 are rejected under 35 U.S.C. § 102(e) as being anticipated by U.S. Patent No. 6,797,002 to Spence et al. (hereafter "Spence"). Insofar as this ground for rejection applies to the present claims, Applicants respectfully traverse.

To establish a prima facie case of anticipation under 35 U.S.C. § 102, the reference must teach every aspect of the claimed invention either explicitly or impliedly. Any feature not directly taught must be inherently present. MPEP 2131. Applicants respectfully submit that this

criterion has not been met for Spence as applied to claims 1, 5-7, 11, 14, and 14 of the present invention, as amended.

Spence lacks elements of the claimed invention. Generally, Spence discusses valve repair apparatus and methods for ensuring proper coaptation and operation of the leaflets of a heart valve. Multiple embodiments are described by Spence, with the Office Action relying primarily on the Spence disclosure with respect to Figs. 22, 22A and 23. The embodiment of Figs. 22, 22A and 23 of Spence appears to be discussed generally in the summary section of the patent. For example, Col. 5, lines 41-56 provide:

> In another aspect of the invention, a device is provided for supporting a heart valve in a patient and generally comprising a support member adapted to be affixed to the annulus and having at least one selectively adjustable portion allowing one section of the support member to be moved with respect to another section thereof and locked in place in order to maintain one or both of the annulus and the leaflets in a desired configuration. The support member may be ring-shaped, for example, and may be selectively adjustable such that one section, lying in a single plane, may be adjusted and angled away from a plane containing another section of the ring-shaped support member. Alternatively, or in addition, the ring-shaped support member may be adjustable to allow one section to be narrowed in width with respect to another section. This feature is also advantageous for correcting ischemic conditions.

The text specifically corresponding to Figs. 22, 22A and 23, is included below (Col. 11, lines 3-27) for convenience.

> FIGS. 22, 22A and 23 illustrate a valve support device 350 for correcting valve malformations such as that shown in FIG. 21. These devices are especially useful for treating ischemic conditions in which one side of the valve pulls away from another side resulting in imperfect coaptation of the valve leaflets. Specifically, device 350 is in the form of a ring-shaped support member 352 having a selectively adjustable and lockable portion 354. As shown best in FIG. 22, ring-shaped support member 352 may be reformed into the shape shown in phantom and retained in that shape. Alternatively, device 350 may be formed with a permanent asymmetric shape about both axes x,y. As shown in FIG. 23, the ***ability to squeeze portion 354 of ring-shaped support member 352 together*** and retain portion 354 in that position will bring valve leaflets 332, 334 together to close gap 338. FIG. 22A illustrates one manner of allowing ***selectively adjustable and lockable***

> ***positioning*** of ring-shaped support member 352. In this regard, respective socket segments 354a, 354b, 354c receive balls 356 therebetween and further receive a wire 358 which may be tensioned and ***locked in place with a set screw 360 by use of a tool 362.*** When wire 358 and socketed segments 354a-d and balls 356 are loosened, adjustability of section 354 is possible. ***Once the adjustment in position is made, wire 358 is tensioned to bring the balls and sockets together and then lock in place using tool 362. This retains the adjusted shape.***

(emphasis added). In sum, Spence discusses an annular implant device that can be re-shaped (e.g., squeezed) by the user and then locked in place using a wire 358 and a set screw 360 that is engaged with a tool 362.

Claim 1 of the present invention is distinguishable over Spence for several reasons. For example, in contrast with Spence, claim 1 of the present application recites, in part: "an implantable device with a body and having an adjustable member configured to adjust the dimensions of the implantable device...." The Office Action asserts the "adjustable member" is anticipated by section 354d of Spence. As noted above, the device described in Spence does not have an adjustable member which is itself configured to adjust the dimensions of the annular implant. Sections 354a-d of Spence are passive members. The implant of Spence must be separately adjusted and then locked in place using a tensioned wire and set screw. Spence does not disclose any specific technique for actually adjusting the dimensions of the implant; but merely states that a tool (362) is used to tighten a set screw (360) that locks the adjusted device in place. The sections 354a-d of Spence are passive and must be manually or otherwise adjusted. Thus, Spence does not disclose an adjustable member which is itself configured to adjust the dimensions of a device. For at least this reason, Applicants submit that Spence does not teach or suggest all the features of claim 1.

Furthermore, claim 1 of the present invention recites, in part: "an adjustment tool configured to actuate the adjustable member and provide for adjustment before, during and after the anatomic orifice or lumen resumes near normal to normal physiologic function...." As noted above, Spence does not disclose any specific technique for actually adjusting the dimensions of the implant. Nothing in Spence teaches or suggests that the adjustment of the implant can be accomplished on an anatomic orifice or lumen during or after it resumes near normal to normal

physiologic function (e.g., once the incision near the anatomic orifice is closed). The only disclosure in Spence that is alleged to enable adjustment of the implant during normal physiologic function is the non-planar orientation of the set screw (360) and tool (362) relating to Fig. 22A. In fact, however, the tightening or loosening of the set screw (360) in Spence provides no indication of how the implant itself would then be adjusted (or "squeezed") once the set screw is loosened (or tightened). Thus, Spence does not teach or suggest "an adjustment tool configured to ... provide for adjustment before, during and after the anatomic orifice or lumen resumes near normal to normal physiologic function." For at least this reason, Applicants submit that Spence does not teach or suggest all the features of claim 1.

As another example, claim 1 of the present invention recites, in part: "wherein the implantable device is adapted to be adjusted on a beating heart...." There is no indication whatsoever in Spence that the disclosed device is itself adapted to be adjusted on a beating heart. In fact, the separate locking and adjusting technique disclosed in Spence clearly indicates that adjustment on a beating heart was not contemplated by its authors. Unlike an open-heart procedure with the patient on a heart by-pass pump, adjustment of an implant device on a beating heart requires a mechanism to remotely adjust the implant device in the confined space of an enclosed closed anatomic orifice. Spence provides no mechanism to adjust the implant once the set screw is moved to an unlocked position. Thus, Spence fails to teach or suggest an implantable device which is itself adapted to be adjusted on a beating heart.

Because Spence fails to teach or suggest at least the elements of claim 1 discussed above, Applicants submit that Spence fails to anticipate the present invention. Claims 5-7, 11, 14, and 24 depend directly or indirectly from claim 1 and are, thus, distinguishable over Spence for at least the same reasons as claim 1.

In light of the foregoing, Applicants respectfully request withdrawal of the rejection of claims 1, 5-7, 11, 14, and 24 under 35 U.S.C. § 102(e) with respect to Spence.

Obviousness rejections based on Spence in view of Ortiz

Claims 2-4 are rejected under 35 U.S.C. 103(a) as being unpatentable over Spence in view of U.S. Patent No. 6,419,696 to Ortiz et al. ("Ortiz"). The rejection is respectfully

traversed.

To establish a prima facie case of obviousness, three criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must by some expectation of success. Third, the prior art references must disclose or suggest all of the claimed features. MPEP 2143. Applicants respectfully submit that these criteria have not been met with respect to the rejected claims.

As describe in the Abstract, Ortiz provides devices for repairing and replacing a heart valve. In various embodiments, the devices include at least first and second support rings connected together in a coiled configuration to abut opposite sides of a valve annulus. A replacement valve may be secured to the coil-shaped device. Various alternative fastening systems include suture fastening systems, mechanical fastening systems, shape memory alloy fastening systems and other fastening systems relying only on the resilience between adjacent coils. The invention contemplates various embodiments of the device, including embodiments for catheter-based surgery and embodiments for open heart surgery.

As noted above, Spence fails to teach or suggest elements of claim 1 from which claims 2-4 depend. Ortiz fails to supply these deficiencies by disclosing a coil-shaped device and various fastening systems. Particularly, Ortiz fails to teach or suggest the various limitations of claim 1 regarding adjustment of the dimensions of an implant device. For at least these reasons, Applicants respectfully submit that Spence and Ortiz, neither separately nor in combination, teach or suggest claims 2-4 of the present invention. Thus, Applicants respectfully submit that claims 2-4 of the present invention are not rendered obvious by Spence in view of Ortiz.

Obviousness rejections based on Spence in view of Ahmadi

Claims 15, 18, and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Spence in view of U.S. Patent No. 4,602,911 to Ahmadi ("Ahmadi"). The rejection is respectfully traversed.

Ahmadi discusses an annular device which engages with a tool. In order for the Ahmadi device and tool to engage, the tool must lie along the plane of the annular device. For example,

as shown in Figs. 5 and 6 of Ahmadi, and as discussed in col. 1, lines 43-45, in order to operate, the Ahmadi tool must be co-planar with the Ahmadi "ringprothesis" device in order to connect to the Ahmadi device ring and in order that the tool may act on the "thrust bearing" that is disposed at a "side opposite the insertion opening" (Col. 1, line 43-45). When in place on tissue, such a tool must lie along a plane of the tissue. Use of a tool in a co-planar orientation would create, at least, significant difficulties in conducting adjustment of an annular device after attachment to adjacent tissue. As applied in the Office Action, Ahmadi is used to teach an adjustment member including teeth engaged with a gear in order to easily and precisely adjust the size of the implant.

As noted above, Spence fails to teach or suggest elements of claim 1 from which claims 15, 18, and 19 depend. Ahmadi fails to supply these deficiencies by disclosing a co-planar adjustment system for an annular device. Particularly, Ahmadi fails to teach or suggest the various limitations of claim 1 regarding adjustment of the dimensions of an implant device. For example, the device of Ahmadi cannot be adapted to be adjusted on a beating heart and cannot provide for adjustment before, during and after the anatomic orifice or lumen resumes near normal to normal physiologic function, as claimed. For at least these reason, Applicants respectfully submit that Spence and Ahmadi, neither separately nor in combination, teach or suggest claims 15, 18, and 19 of the present invention. Thus, Applicants respectfully submit that claims 15, 18, and 19 of the present invention are not rendered obvious by Spence in view of Ahmadi.

Obviousness rejections based on Spence in view of Gabbay

Claims 6-9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Spence in view of U.S. Patent No. 6,368,348 to Gabbay ("Gabbay"). The rejection is respectfully traversed.

As described in the Abstract, Gabbay provides an annuloplasty prosthesis for supporting an annulus of a heart valve which includes a substrate material over which a covering of a biocompatible and biological tissue material is applied. As applied in the Office Action, Gabbay is used to teach an implantable device having a fastener device including a plurality of grommets and sutures to fasten the device.

As noted above, Spence fails to teach or suggest elements of claim 1 from which claims 6-9 depend. Gabbay fails to supply these deficiencies by disclosing a fastener device including a plurality of grommets and sutures. Particularly, Gabbay fails to teach or suggest the various limitations of claim 1 regarding adjustment of the dimensions of an implant device. For at least these reason, Applicants respectfully submit that Spence and Gabbay, neither separately nor in combination, teach or suggest claims 6-9 of the present invention. Thus, Applicants respectfully submits that claims 6-9 of the present invention are not rendered obvious by Spence in view of Gabbay.

Obviousness rejections based on Spence in view of Northrup

Claims 1, 6, 9, and 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Spence in view of U.S. Publication No. 2002/0128708 to Northrup et al. ("Northrup"). The rejection is respectfully traversed.

As described in the Abstract, Northrup provides an apparatus for stabilizing an anatomical structure that includes a combination of repeating rigid elements within a single flexible element. While applicable to routine open surgical techniques and to a variety of anatomical structures, the system is especially applicable to minimally invasive endoscopic/robotic mitral valve repair. The apparatus can be cut to size prior to attachment to fit a particular application. As applied in the Office Action, Northrup is used to teach techniques to aid in fastening the device to the orifice or lumen.

As noted above, Spence fails to teach or suggest elements of claim 1 from which claims 6, 9 and 12 depend. Northrup fails to supply these deficiencies by disclosing a fastener device including a plurality of grommets and sutures. Particularly, Northrup fails to teach or suggest the various limitations of claim 1 regarding adjustment of the dimensions of an implant device. For example, the device of Northrup cannot be adapted to be adjusted on a beating heart and cannot provide for adjustment before, during and after the anatomic orifice or lumen resumes near normal to normal physiologic function, as claimed. For at least these reason, Applicants respectfully submits that Spence and Northrup, neither separately nor in combination, teach or suggest claims 6-9 of the present invention. Thus, Applicants respectfully submit that claims 1,

6, 9, and 12 of the present invention are not rendered obvious by Spence in view of Northrup.

Allowable subject matter

Applicants wish the thank the Examiner for the indication that claims 13, 16-17 and 20-23 contain allowable subject matter. These claims remain as previously presented in light of the above remarks concerning the claims from which claims 13, 16-17 and 20-23 depend.

CONCLUSION

In view of the foregoing, Applicants submit that this application is in condition for allowance, and such disposition is earnestly solicited. If the Examiner believes that the prosecution of this case might be advanced by discussing the application with Applicants' representative, in person, or over the telephone, Applicants' representatives would welcome the opportunity to do so.

EXCEPT for fees payable under 37 CFR §1.18, the Commissioner is hereby authorized by this paper to charge any additional fees during the entire pendency of this application, including fees due under 37 CFR §1.16 and 1.17 which may be required, including any required extension of time fees, or credit, any overpayment to deposit account No. 50-1349. This paragraph is intended to be a constructive petition for extension of time in accordance with 37 CFR §1.136(a)(3).

Respectfully submitted,

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